No. 84-1620

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

—v.—

CIBA-GEIGY CORPORATION,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

RANDOLPH S. SHERMAN
425 Park Avenue
New York, New York 10022
(212) 407-8000

Attorney for Respondent

Of Counsel:

MILTON HANDLER
RICHARD A. DE SEVO
Kaye, Scholer, Fierman, Hays & Handler
425 Park Avenue
New York, New York 10022

FREDERICK L. WHITMER
Pitney, Hardin, Kipp & Szuch
163 Madison Avenue, CN 1945
Morristown, New Jersey 07960

GARY S. FREEDMAN
MIRIAM LANE SPARROW
CIBA-GEIGY Corporation
556 Morris Avenue
Summit, New Jersey 07901

COUNTERSTATEMENT OF QUESTION PRESENTED

Does this case warrant the sparing exercise of this Court's extraordinary certiorari jurisdiction: (a) where the judgment affirmed by the Court of Appeals rested upon two *alternative* findings of liability under state as well as federal unfair competition law—the tort of "unprivileged imitation" and the tort of "passing off"; and (b) where, contrary to petitioner's assertion, neither finding is in conflict with this Court's decision in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), because:

—With respect to the tort of "unprivileged imitation":

(a) The Court of Appeals *affirmed* the trial court's *factual* finding of "nonfunctionality" as not being clearly erroneous, whereas in *Ives*, in the context of a claim of contributory trademark infringement, the Second Circuit *reversed* the trial court's *factual* finding of "functionality" *without* applying the clearly erroneous test; and

(b) The Court of Appeals *affirmed* the trial court's *factual* finding of "secondary meaning" as not being clearly erroneous, whereas in *Ives* this Court did not even address the sufficiency of the evidence necessary to establish "secondary meaning"; and

—With respect to the *alternative* holding of "passing off":

(a) The Court of Appeals explicitly did "not decide" the purported conflict between the trial court's application of the "reasonable anticipation" standard for the tort of "passing off" under § 43(a) of the Lanham Act and *Ives'* rejection of that test for contributory infringement under § 32 of the Lanham Act, the Court of Appeals instead holding that the trial judge's *factual* finding that petitioner acted with the intent to induce passing off 'differ[ed] markedly" from the factual findings in *Ives*

and "constitute[d] the prerequisite predicate" for a § 43(a) violation;

(b) *Ives* dealt only with the propriety of the "reasonable anticipation" standard for a claim of contributory infringement under § 32 of the Lanham Act and *not* for a claim of "passing off" under § 43(a) of the Act, which this Court noted in *Ives* "prohibits a broader range of practices than § 32"; and

(c) The District Court *alternatively* held that the "reasonable anticipation" standard governed the tort of "passing off" under New Jersey unfair competition law and that the facts supported such a state law violation—a finding that the Court of Appeals affirmed as not being clearly erroneous?

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STATEMENT PURSUANT TO SUPREME COURT RULE 28.1

CIBA-GEIGY Corporation, a privately-owned New York corporation, states that its parent is CIBA-GEIGY Ltd., a Swiss corporation. Each company's subsidiaries are wholly owned.

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RESPONDENT'S BRIEF IN OPPOSITION

Respondent CIBA-GEIGY Corporation ("CIBA") respectfully submits that the instant Petition fails to present a single "special and important" reason warranting the issuance of a writ of certiorari. (*See* Sup. Ct. Rule 17). On the contrary, the only issue raised by the disposition below is whether the Court of Appeals correctly affirmed the District Court's findings of fact—which provided several *alternative* bases for its judgment under state and federal law—on the ground that those findings were not "clearly erroneous" under Rule 52(a) of the Federal Rules of Civil Procedure. Because that fact-bound determination presents no conflict with any decision of this Court or any other Circuit, and because this Court's extraordinary certiorari jurisdiction is not properly invoked "to review evidence and discuss specific facts,"[1] the Petition should be denied.

1 United States v. Johnston, 268 U.S. 220, 227 (1925).

STATEMENT OF THE CASE

The Petition presents an incomplete, misleading and distorted version of both the relevant facts and the proceedings below—not the least of which is its mischaracterization of the grounds for the Third Circuit's affirmance. The salient evidentiary facts are set forth in what the Court of Appeals described as the "thoughtful and detailed opinion" of the District Court (A. 4), and will not be repeated here except insofar as necessary to a proper understanding of the rulings below. Suffice it to say that the Petition presents a one-sided statement of the case, which largely ignores the District Court's fact findings and the substantial supporting evidence which led the Third Circuit to sustain those findings as not being clearly erroneous.[2]

A. The Preliminary Injunction Proceedings in the District Court

CIBA commenced this action on March 12, 1982, alleging that petitioner Bolar Pharmaceutical Co., Inc. ("Bolar") had violated both the federal and New Jersey state law of unfair competition by intentionally duplicating the trade dress of CIBA's brand name prescription drug APRESAZIDE.[3] On March 17, 1982, the District Court temporarily restrained

2 Similarly, the *amicus* briefs of the National Council of Senior Citizens, the Illinois Pharmacists Association and the Generic Pharmaceutical Industry Association ("GPIA") are replete with factual statements and assumptions which are not only outside of, but contrary to the record underlying the District Court's fact findings. As this Court recently noted, "[t]he stated desires of *amici* concerning the outcome of this or any litigation . . . are not evidence in the case, and do not influence our decision. . . ." Sony Corp. v. Universal City Studios, Inc., 104 S. Ct. 774, 785 n.16 (1984).

3 The term "trade dress" is used here, as it was by the courts below, in its "modern sense" to refer to the physical appearance of CIBA's APRESAZIDE products. *See* Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 80 n.2 (3d Cir. 1982). "APRESAZIDE," a federally registered trademark, is CIBA's brand name for its antihypertensive combination products containing the drugs hydralazine hydrochloride and hydrochlorothiazide.

Bolar from selling its generic version of CIBA's product in confusingly similar trade dress and ordered Bolar to show cause why such conduct should not be preliminarily enjoined. (A. 10).

After a three-day evidentiary hearing at which seven witnesses testified and 162 exhibits were admitted into evidence (A. 11), the District Court granted CIBA's motion for a preliminary injunction. The reasons for the injunction's issuance were thoroughly set forth in a 41-page opinion which constituted the District Court's findings of fact and conclusions of law. (A. 8-50). In particular, the District Court held that CIBA was likely to establish at trial that Bolar's intentional duplication of APRESAZIDE's trade dress constituted two independent violations of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the New Jersey law of unfair competition—the separate torts of "unprivileged imitation" and "passing off." (A. 35-44, 44-47). As the trial judge took pains to note, that determination was:

> . . . based upon a careful review of the entire record, an appraisal of the witnesses' credibility and demeanor and the reasonable inferences to be drawn therefrom. . . . (A. 11).

The District Court first addressed the two elements of "unprivileged imitation" under § 43(a) of the Lanham Act and New Jersey law—nonfunctionality and secondary meaning.[4] With respect to the former, the trial judge held that this Court's "narrow" ruling in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), did not preclude it as a matter of law "from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40). And based upon that evidence, the

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4 Consistent with prior precedent, the trial judge noted that, "except for the federal law's interstate commerce requirement"—which was plainly satisfied—" 'the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same. . . .' " (A. 34 n.11).

District Court found that the adoption of APRESAZIDE's trade dress "ha[d] nothing to do with the purpose or performance of the drug, or with its processing" and that there was "no medical, pharmaceutical or manufacturing reason" that had either required CIBA to select the trade dress or had compelled Bolar to copy it. (A. 19-20, 35-36).[5]

In finding that APRESAZIDE's trade dress was nonfunctional, the Court also rejected, on the facts before it, each of Bolar's functionality arguments, the "principal" one being that "patients with chronic illnesses such as hypertension identify the trade dress of their medications with the medical condition for which they are prescribed and that, accordingly, it is necessary for generic equivalents to duplicate the physical appearance of their brand name counterparts in order to prevent patient confusion and anxiety" unless illegal substitution occurs. (A. 21). Based on the testimony of Bolar's own medical expert, the District Court found that any "fears or anxieties of the patient" caused by a different-appearing generic equivalent are "invariably" allayed by an explanation from his physician or pharmacist—which is "standard medical and pharmacy practice"—and that any "temporary anxiety is immediately dissipated." (A. 21-23, 37-38). On the other hand, if the generic substitute is identical in appearance to the brand name drug, those patients who *choose* to remain on the brand name product but are dispensed the generic "may never know that it derives from a different source." (A. 38).

Turning to the second element of "unprivileged imitation," the District Court applied the "well-settled legal criteria for determining secondary meaning" to the record facts, and held

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5 In support of this conclusion, the Court found, among other things, that another pharmaceutical manufacturer "has been successfully marketing" distinctly different-colored capsules "as generic alternatives" to APRESAZIDE; that the Food and Drug Administration has "declined to *require*" that generic equivalents be sold in the same trade dress as their brand name counterparts; and that the New Jersey Drug Formulary has taken the "official position" that "differences [in appearance] do *not* affect how well the medication works." (A. 20-21; emphasis in original).

that CIBA had demonstrated "a strong likelihood of ultimate success" on this issue as well. (A. 24).[6] In brief, the Court based this finding on:

> (a) the extended, continuous and exclusive use by CIBA-GEIGY of APRESAZIDE's trade dress; (b) the extensive and costly activities of CIBA-GEIGY in promoting its APRESAZIDE products and their distinctive and arbitrary trade dress; (c) the commercial success that CIBA-GEIGY's APRESAZIDE products have achieved in the market place; and (d) Bolar's intentional copying of APRESAZIDE's trade dress. . . . (*Id.*)

With specific reference to the last factor, the District Court found that "Bolar deliberately copied the trade dress of CIBA-GEIGY's APRESAZIDE capsules for its own economic advantage" and that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of CIBA-GEIGY's APRESAZIDE products." (A. 18).[7]

As an *alternative* basis for its ruling, the District Court also held that CIBA had demonstrated the requisite likelihood of success with respect to the separate tort of "passing off" under both § 43(a) of the Lanham Act and New Jersey law. (A.

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6 In discussing the "well-settled" legal criteria for determining secondary meaning (A. 40-41), the trial judge expressly took account of this Court's *dictum* in *Ives* that "[t]o establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." (456 U.S. at 851 n.11).

7 In holding in CIBA's favor on secondary meaning, the Court also rejected as unsupported Bolar's contention that "APRESAZIDE" had become the generic name of the products in suit, thereby rejecting Bolar's contention that patients' association of the APRESAZIDE brand name with the products' trade dress could not support a finding of secondary meaning. (A. 29, 43). On the contrary, the trial judge found that "[t]he record establishes that hydralazine hydrochloride/hydrochlorothiazide is the commonly recognized generic name of the products in suit" and that Bolar had "consistently used it as such." (A. 29).

44-47). In particular, based upon (1) the likelihood of confusion between APRESAZIDE and Bolar's look-alike capsules; (2) the "economic incentive" for pharmacists illegally to substitute Bolar's products for CIBA's; (3) the "all too prevalent" existence of illegal substitution by pharmacists;[8] and (4) the fact that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its [generic equivalents] at the expense of CIBA-GEIGY's APRESAZIDE products," the trial judge found that Bolar's "duplication of APRESAZIDE's trade dress would facilitate illegal substitution" and that Bolar "reasonably anticipated that its look-alike capsules would be passed off by pharmacies as CIBA-GEIGY's APRESAZIDE products to a not insignificant degree." (A. 29-30, 31, 45, 47). On this basis, the Court concluded that CIBA was likely to prevail at trial on its claim of "passing off" under § 43(a) and New Jersey law, holding that the "reasonable anticipation" standard for that tort was unaffected by this Court's limited disposition in *Ives*. (A. 45-46).[9] Moreover, even assuming that *Ives* had been a "passing off" case under § 43(a)—which it was not—the District Court went on to find "alternatively" that "there is a substantial likelihood that plaintiff will succeed in proving that Bolar *actually intended* to facilitate . . . illegal substitution among pharmacists in order to increase its sales"; and that, accordingly, CIBA had satisfied even *Ives'* standard. (A. 30-31, 46-47; emphasis added).

Finally, the District Court concluded that an injunction against Bolar's conduct was "necessary to protect the public interest." (A. 49). Noting that "the public will be harmed by the existence of defendant's [look-alike] product because it permits, if not encourages, illegal substitution," the trial judge held that "the public interest will be served by the issuance of a

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8 In support of this conclusion, the Court took judicial notice of the fact that 93 pharmacists and pharmacies in New York City were recently *convicted* of engaging in illegal substitution, and that criminal charges remained outstanding against another 61. (A. 31 n.9).

9 *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1062-63 (3d Cir. 1980).

preliminary injunction which, in effect, will prohibit the facilitation of illegal substitution." (A. 49). And if Bolar actually intended such facilitation—which the Court found that CIBA had a substantial likelihood of ultimately proving—"all the more reason why injunctive relief is appropriate." (*Id.*) Moreover, the Court noted, "[e]ven in the case of legal substitution, Bolar's conduct endangers the public interest by jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution." (*Id.*)[10]

On the foregoing basis, the District Court entered an order preliminarily enjoining Bolar from "using any simulation, imitation or substantial duplication of [CIBA's] distinctive trade dress . . . in connection with . . . [Bolar's] hydralazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension." (A. 6). Without seeking a stay of that injunction, Bolar appealed to the Third Circuit.

B. The Court of Appeals' Preliminary Injunction Affirmance and This Court's Denial of Review

On October 14, 1983, the Third Circuit, in a *per curiam* opinion, unanimously affirmed the District Court's preliminary injunction. (A. 3-4). Finding "no merit" to Bolar's arguments for reversal, the Court of Appeals stated:

> After reviewing the record, the briefs and arguments of the parties, and Judge Sarokin's thoughtful and detailed opinion, we hold that the district court did not abuse its discretion, commit an obvious error in applying the law, or make a serious mistake in considering the proof. (A. 4).

As for Bolar's contention that the district judge had erred in failing to read *Ives* as overruling the "reasonable anticipation"

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10 As the District Court noted, the Illinois Drug Formulary, among others, "specifically provides that drug substitution may not occur unless, *inter alia,* the 'informed' patient agrees to the substitution." (A. 23 n.7).

standard for the tort of "passing off" under § 43(a), the Third Circuit noted in a footnote that "we need not address this issue" because that standard was nevertheless "mandated" under New Jersey law; and because, in any event, under both § 43(a) and state law, the District Court's alternative holding with respect to "unprivileged imitation" provided "a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief." (A. 4 n.1).

This Court thereafter denied Bolar's petition for certiorari to review the Third Circuit's preliminary injunction affirmance. 104 S. Ct. 1444 (1984).

C. The District Court's Entry of Final Judgment

In December 1983, at Bolar's urging and with CIBA's consent, the District Court converted the preliminary injunction hearings to "the final trial on the merits" and entered a final judgment in CIBA's favor. (A. 52-55). Concluding that "on the present record and for the reasons set forth in its opinion of August 11, 1982, CIBA-GEIGY is entitled to final relief," the District Court ordered that "the preliminary injunction issued on October 4, 1982 is made permanent." (A. 54-55). In so ruling, the District Court "implicitly converted its [earlier] findings of a 'likelihood of success' on the merits to findings of 'success' on the merits." (A. 66). Bolar then appealed again to the Third Circuit.

D. The Third Circuit's Affirmance and Denial of Rehearing *En Banc*

On November 2, 1984, the same Third Circuit panel which had unanimously affirmed the District Court's preliminary injunction this time affirmed its final judgment by a 2-to-1 vote.

At the outset, Judge Higginbotham, who was joined in the majority by Judge Hunter, identified the four key factual findings which formed the predicate for the District Court's

alternative holdings with respect to the torts of "unprivileged imitation" and "passing off":

> CIBA proved (1) that the trade dress of APRESAZIDE was non-functional; (2) that APRESAZIDE had acquired secondary meaning with an identifiable group of users of anti-hypertensives; (3) that Bolar could reasonably anticipate that some pharmacists provided with Bolar's generic hydralazine hydrochloride/hydrochlorothiazide would attempt to illegally substitute it for CIBA's APRESAZIDE; and (4) that Bolar copied CIBA's APRESAZIDE trade dress with the intent, at least in part, to facilitate the illegal substitution of Bolar's generic drug for CIBA's brand name drug. (A. 69).[11]

The majority then turned to the District Court's holding of "unprivileged imitation" and, after summarizing the relevant evidence, sustained that holding under both state and federal law on the ground that the trial judge's fact findings of nonfunctionality and secondary meaning were not clearly erroneous. Judge Higginbotham could not have been clearer that this was the basis for the Court's disposition:

> Judge Sarokin's finding of nonfunctionality is a finding of fact. A finding of fact is clearly erroneous when the reviewing court is left with the 'definite and firm conviction that a mistake has been committed.' [Citations omitted]. *We believe in this case appellant Bolar failed to prove that the district court's finding was clearly erroneous.*
>
> * * *

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11 Although the trial court had not "expressly recast" its preliminary injunction findings to conform with its grant of final relief, the Court of Appeals carried out that "mechanical task" in order "to ensure that the district court's conversion of its preliminary injunction does not become the basis of another appeal." (A. 64). Accordingly, the Third Circuit "treated the district court's findings that plaintiff has demonstrated 'likelihood of success' on the merits as findings that plaintiff 'succeeded' on the merits." (A. 66).

Based on this evidence *we cannot say that the district court's finding of non-functionality was clearly erroneous.*

* * *

[W]e turn to the final element [of a successful claim of unprivileged imitation]—*whether the district court's finding that the trade dress of APRESAZIDE capsules had acquired a secondary meaning was clearly erroneous.* The district court found that CIBA met its burden. *We agree.*

* * *

Because the district applied the correct legal standard [for secondary meaning], we must decide *only whether the district court's finding that APRESAZIDE patients identify those products with CIBA is clearly erroneous.* If we cannot say with firm conviction that its finding was clearly erroneous, we cannot reverse on this issue.

* * *

[W]e cannot say with firm conviction that a mistake was made by the district court in finding secondary meaning in APRESAZIDE's trade dress. *Because the district court's finding of secondary meaning was not clearly erroneous, it therefore must be upheld.*

* * *

To establish unprivileged imitation under the [Lanham] Act, a plaintiff must prove the nonfunctionality of the imitated feature and must prove secondary meaning of the imitated feature. These proofs are essentially the same as those required for unprivileged imitation under New Jersey law. [Citation omitted]. *Because the district court's findings of fact with respect to the New Jersey claim were not clearly erroneous, its findings of fact necessary to the proof of CIBA's federal claim were also not clearly erroneous.* (A. 71-73, 75, 79-80; emphasis added).

Turning to the District Court's *alternative* holding of "passing off," Judge Higginbotham first addressed the "requisite

proofs" for that tort under New Jersey law as "recently articulated"—that " 'it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product. . . .' " (A. 76; citation omitted). Applying this *state* law standard to the record evidence, the majority sustained the District Court's finding that Bolar was guilty of "passing off" under New Jersey law:

> It was *not clearly erroneous* for the district court to find . . . that Bolar copied APRESAZIDE with the reasonable anticipation that pharmacists would illegally substitute Bolar's drug for CIBA's. (A.77; emphasis added).

With respect to the trial judge's *alternative* holding of "passing off" under federal law, Judge Higginbotham found that, while it was "debatable" whether *Ives* had jettisoned the "reasonable anticipation" standard in § 43(a) cases, it was "unnecessary" for the Court to decide that issue because the District Court's "factual findings and our review of them in this case *differ markedly* from the findings and their appellate review in *Ives*." (A. 80; emphasis added). As Judge Higginbotham elaborated:

> In contrast to the findings made by the trial judge exculpating the generic drug manufacturer [under § 32 of the Lanham Act] in *Ives, the findings made by the trial judge in this case implicate Bolar and constitute the prerequisite predicate for holding that there was a violation of section 43(a) of the Lanham Act.* Here, *inter alia*, the district court expressly found that Bolar's generic alternative could be mistaken for CIBA's APRESAZIDE, that many pharmacists had been convicted of illegal substitution in New York, that Bolar copied APRESAZIDE's trade dress with intent to increase sales of its generic alternative at the expense of CIBA, and that Bolar copied CIBA's trade dress with the intent, at least in part, to induce illegal substitution. Irrespective of the analysis

by the trial court as to the significance of footnote 13 in the *Ives* opinion, *on the basis of the record before us, we cannot say with definite and firm conviction that the trial court's finding of intent to facilitate illegal substitution was in error.* Just as the trial judge should not have been reversed by the Court of Appeals in *Ives, Judge Sarokin in this case, having had the opportunity to evaluate the credibility of witnesses and weigh the evidence, must be sustained on this issue because his findings are not clearly erroneous.* (A. 81-82; emphasis added).

Finally, the majority held that the District Court's "equitable finding concerning the public interest was not in error," noting that "[t]he evidence supports a finding that the practice of illegal substitution occurs and that its full extent cannot be shown." (A. 77-78). While Bolar's argument that it was in the public interest to copy APRESAZIDE's trade dress was "not necessarily frivolous," Judge Higginbotham concluded that "the district court could find, without being in error, that the greater damage to the public would result from the production of look-alike capsules." (A. 78 n.5).

As Judge Higginbotham correctly observed, the dissenting opinion—written by Judge Giles of the Eastern District of Pennsylvania—"devote[d] one-third of its discussion to an issue which [the majority] did not decide" (A. 83 n.10)—whether *Ives* overruled the "reasonable anticipation" standard for the tort of "passing off" under § 43(a) of the Lanham Act. (A. 83, 91-95).[12] Moreover, as to the ground on which the majority actually affirmed the District Court's "passing off" holding under § 43(a)—that it was not clearly erroneous for the trial judge to have found that Bolar had actually intended

12 Apparently realizing this, the dissent nevertheless believed it was desirable to resolve the issue in order to "provide necessary guidance to the lower courts within this Circuit." (A. 83). This, of course, would have been tantamount to giving an advisory opinion—a process in which the panel's majority correctly declined to engage. Nor did the full Court feel such "guidance" was necessary, since it subsequently denied rehearing *en banc*. (A. 105).

to induce illegal substitution—the dissent's sole disagreement was over the sufficiency of the evidence. In other words, Judge Giles would have held that "the district court's finding of intent to induce" was "clearly erroneous." (A.96).

Similarly, the dissent's sole disagreement with the majority over the District Court's "unprivileged imitation" holdings centered on the sufficiency of the evidence—and then only as it related to the element of secondary meaning. Indeed, Judge Giles explicitly "agree[d] with the majority's analysis and conclusions with respect to functionality," and acknowledged that the District Court had "articulated the appropriate legal standard for secondary meaning under both New Jersey and federal law. . . ." (A. 83-84). His view was simply that there was "insufficient evidence" to support a fact finding of secondary meaning. (A. 84).

Following the panel's affirmance, Bolar petitioned the Third Circuit for rehearing or rehearing *en banc*. On January 8, 1985, that petition was denied, "no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges in the circuit in regular active service not having voted for rehearing by the court in banc. . . ." (A. 105). Thereafter, Bolar filed the instant Petition.

REASONS FOR DENYING THE WRIT

I. The Sparing Exercise of This Court's Extraordinary Certiorari Jurisdiction Is Not Warranted to Determine Whether the Record Evidence Sufficiently Supported the District Court's Fact Findings Under the Clearly Erroneous Standard.

A. The Lower Court's Fact Findings With Respect to the Tort of "Unprivileged Imitation" Present No Conflict With This Court's Narrow Disposition in *Ives*.

Contrary to Bolar's contention (Petition at 9, 11, 18-30), the Third Circuit's affirmance of the District Court's "unprivileged imitation" holdings under state and federal law does not

"conflict" with this Court's limited disposition in *Ives* or with the Second Circuit's remand decision in that case—either with respect to nonfunctionality or secondary meaning, the two constituent elements of that tort.

Insofar as nonfunctionality is concerned, the difference in result between this case and *Ives* is attributable not to any conflict in legal standards, but solely to the fact that two trial judges, after evaluating the credibility of the witnesses and weighing the evidence before them, reached different factual conclusions with respect to the issue—hardly a matter which is worthy of certiorari. As for secondary meaning, this Court did not even address the issue in *Ives*, except in a passing footnote which the trial judge and the Court of Appeals here expressly took into account. The Third Circuit's holding that the trial judge's finding of secondary meaning was not clearly erroneous is simply another fact-bound determination which does not warrant the grant of certiorari.

1. Nonfunctionality

Contrary to Bolar's contention, the District Court did not "apply[ ] an improper legal standard for determining functionality. . . ." (Petition at 25). In fact, the trial judge quoted precisely the legal standard for functionality enunciated by this Court in *Ives* and, applying that standard to the evidence before him, found as a matter of fact that APRESAZIDE's trade dress was nonfunctional. (*See* A. 35). Nor did the Third Circuit apply an improper legal standard in affirming that fact finding as not being clearly erroneous. Indeed, even the dissenting judge expressly "agree[d] with the majority's analysis and conclusions with respect to functionality." (A. 84).[13]

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13 In *Ives*, this Court noted that "[i]n general terms, a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." (456 U.S. at 850 n.10). Applying that definition here, the District Court was plainly correct in finding APRESAZIDE's trade dress to be nonfunctional. As the trial judge found on the facts before him, APRESAZIDE's trade dress "ha[d] nothing to do with the purpose or performance of the drug, or with its processing" and that there was "no medical, pharmaceutical

As Judge Higginbothom noted below, any "assertion that *Ives* held that trade dress is functional as a matter of law is incorrect." (A. 79 n.7). The narrow issue resolved by this Court in *Ives* was whether the Second Circuit had exceeded the scope of its appellate review by reversing the trial court's holding that the defendants' duplication of the plaintiff's trade dress for its CYCLOSPASMOL product did not constitute contributory trademark infringement in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114. While the district court

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or manufacturing reason" that either had required CIBA to select the trade dress or had compelled Bolar to copy it. (A. 19-20, 35-36). Moreover, as the Court of Appeals noted, the record established that "generic equivalents to APRESAZIDE can be manufactured in different sizes, shapes or colors without added cost." (A. 77). Indeed, Bolar concedes that CIBA's choice of APRESAZIDE's trade dress was "arbitrary." (Petition at 5).

Nevertheless, Bolar argues that the District Court's functionality holding is at odds with "[a]nother common definition of functionality" which Bolar claims the Second Circuit used in *Ives*—that is, "[a] particular feature of an article is functional if it 'is an important ingredient in the commercial success of the product. . . .' " (Petition at 24). To begin with, that so-called test was not approved by this Court in *Ives*. Moreover, the Second Circuit itself has recently criticized the "commercial success" definition of functionality as "confusing" and "overinclusive," since "[t]rade dress associated with a product that has accumulated goodwill . . . will most always be 'an important ingredient' in the 'saleability' of the product." LeSportsac Inc. v. K Mart Corp., 754 F.2d 71, 77 (2d Cir. 1985); Warner Bros., Inc. v. Gay Toys, Inc., 724 F.2d 327, 330 (2d Cir. 1983). This dim view of the "commercial success" test is taken by other Circuits as well. *See, e.g.*, Sicilia Di R. Biebow & Co. v. Cox, 732 F.2d 417, 428 (5th Cir. 1984):

> To define functionality in terms of commercial success or marketing effectiveness . . . would permit a second comer to copy the distinctive dress of a product whenever it became successful and consumers became accustomed to its dress. [Citation omitted.] We do not doubt that such copying would enable the second comer to market his product more effectively, but the Lanham Act does not permit that result.

In effect, adoption of the "commercial success" test for functionality would make it impossible for a plaintiff ever to establish "unprivileged imitation," for proof of that tort's other element—secondary meaning—would *ipso facto* disprove nonfunctionality.

in *Ives* had also rejected plaintiff's § 43(a) claim on the facts before it, neither the Second Circuit nor this Court had reached that holding. (456 U.S. at 853, 858-59).

In deciding the § 32 issue in *Ives,* this Court noted that "[w]hile the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act"—the statutory provision relied upon here—"a finding of functionality may also be relevant to an action involving § 32," since it tends to indicate "a legitimate reason for producing an imitative product." (456 U.S. at 858 n.20). In that limited context, this Court held that the Second Circuit had committed reversible error by "substitut[ing] its interpretation of the evidence for that of the trial court" without first rejecting the District Court's fact finding of functionality as "clearly erroneous" under Rule 52(a). (*Id.* at 855, 857). As Justice O'Connor explained:

> The appellate court was not entitled simply to disregard the District Court's finding of functionality. . . . If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous. (*Id.* at 858 n.20).

This Court's precise holding—that "[t]he Court of Appeals erred in setting aside *findings of fact* that were not clearly erroneous" (*id.* at 858; emphasis added)—puts the lie to any contention that *Ives* ruled that all drug trade dress is functional as a matter of law.[14]

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14 Indeed, this Court did not even view the trial court's factual finding of functionality in *Ives* as dispositive of plaintiff's § 43(a) claim. Instead, it remanded the case to the Second Circuit for an "independent review" of that claim. (456 U.S. at 858-59). Had the Court held that drug trade dress was functional as a matter of law, that remand would have been unnecessary. Nor did the Second Circuit on remand view this Court as holding that drug trade dress was functional as a matter of law. Rather, the Second Circuit affirmed the dismissal of plaintiff's § 43 claim on the basis of the trial judge's *factual* findings which the Second Circuit held could not be "label[ed] . . . clearly erroneous." (A. 59). In this connection, it is noteworthy that the

The critical distinction between this case and *Ives* is that here the Third Circuit *affirmed* a district court fact finding of nonfunctionality as not being clearly erroneous, whereas in *Ives* the Second Circuit *reversed* a fact finding of functionality without holding it clearly erroneous. Thus, the District Court correctly held that "[n]othing in *Ives* precludes this court from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40).[15]

Viewed properly, then, the only issue presented by Bolar with respect to functionality is whether the Third Circuit erred in affirming the District Court's fact finding of nonfunctionality as not being clearly erroneous—an issue that hardly merits the sparing exercise of this Court's certiorari jurisdiction. Indeed, in *Ives* itself, Justice White stated that "if the issue presented in the petitions for certiorari had been whether the clearly erroneous standard, although properly invoked, was erroneously applied, it is doubtful in my mind that this

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Second Circuit's remand opinion was "not published pursuant to Second Circuit Rule 0.23" (*see* A. 60)—which means that "each judge believe[d] that no jurisprudential purpose would be served" by such publication. (2d Cir. R. 0.23). If, in fact, the Second Circuit had read *Ives* to hold that all drug trade dress was functional as a matter of law, it surely would have been of sufficient "jurisprudential" import to have warranted the opinion's publication.

15 For the same reason, the Court of Appeals' affirmance in this case is not in conflict with the Second Circuit's remand decision in *Ives*. As already noted (*see* p. 16 n.14, *supra*), on remand in *Ives*, the Second Circuit simply affirmed the trial judge's fact findings as not being clearly erroneous, which is precisely what the Third Circuit did here. Thus, the difference in result in the two cases turned solely on the trial judges' different assessments of the facts before them, including issues of credibility. Nor is Bolar correct that "[t]he facts in this case are the same as the facts . . . in *Ives*." (Petition at 8). For example, in *Ives* there was evidence before the district judge that it was difficult to sell a non-look-alike version of CYCLOSPASMOL to hospitals, pharmacies and wholesalers and that, indeed, the defendant's parent had discontinued the sale of a non-look-alike product for that reason. (488 F. Supp. at 399). Here, in marked contrast, the record demonstrated that another pharmaceutical manufacturer was "successfully marketing" distinctly different-looking capsules "as generic alternatives" to APRESAZIDE and that Bolar could have done the same and secured a "strong market position." (A. 20, 48).

fact-bound issue would have warranted certiorari." (456 U.S. at 859). Justice White's skepticism reflects this Court's long-standing view that "[w]e do not grant certiorari to review evidence and discuss specific facts." *United States* v. *Johnston*, 268 U.S. 220, 227 (1925). As this Court's "repeated pronouncements" have made clear, "it 'cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.' " *Berenyi* v. *Immigration Director*, 385 U.S. 630, 635 (1967), *quoting Graver Mfg. Co.* v. *Linde Co.*, 336 U.S. 271, 275 (1949). No such "obvious and exceptional" showing has been or could be made here given the ample evidentiary support for the District Court's nonfunctionality finding. (*See* A. 1924).

2. Secondary Meaning

As previously noted, in finding that APRESAZIDE's trade dress had achieved secondary meaning, the trial judge applied "the well-settled legal criteria for determining secondary meaning." (A. 24). Moreover, in affirming that factual finding as not being clearly erroneous, the Third Circuit held that "the district court applied the correct legal standard." (A. 73). Indeed, even a cursory review of the District Court's opinion demonstrates that the factors on which it relied in finding secondary meaning—including Bolar's intentional copying of APRESAZIDE's trade dress—are the very criteria that the courts throughout the Circuits have traditionally applied in determining this element of unprivileged imitation. (A. 24-25, 40-41).[16]

Nevertheless, Bolar contends that these traditional factors are "logically inapplicable" in the pharmaceutical industry and

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16 *See, e.g.*, Thompson Medical Co. v. Pfizer Inc., 753 F.2d 208, 217 (2d Cir. 1985); Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 82 (3d Cir. 1982); Faberge, Inc. v. Saxony Prods., Inc., 605 F.2d 426, 428 (9th Cir. 1979); Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1220 & n.13 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976). *See* J. McCarthy, *Trademarks & Unfair Competition* § 15.16 (1973); J. Gilson, *Trademark Protection & Practice* § 2.09[1] (1982).

should, in that context, be "rejected as a matter of law as proof of secondary meaning." (Petition 20, 22). Yet the facts in this case demonstrate the inappropriateness of any such hard and fast rule. For example, contrary to Bolar's contention, the District Court did not infer secondary meaning here based solely on the act of copying. Rather, the trial judge found that Bolar had copied APRESAZIDE's trade dress *without legitimate justification*—its "principal motivation" being to "increase sales" of its look-alike capsules at the "expense of [CIBA's] APRESAZIDE products" and to do so, at least in part, by inducing illegal substitution. (A. 18, 30, 46). In making those fact findings, the District Court rejected the testimony of Bolar's president that defendant had copied APRESAZIDE's trade dress for proper purposes—a matter of credibility uniquely within the trial judge's province. *See Anderson* v. *City of Bessemer*, 105 S. Ct. 1504, 1511-13 (1985). Moreover, unlike the defendants in *Ives*, Bolar could not rely on the functionality of APRESAZIDE's trade dress as "a legitimate reason for producing an imitative product" (456 U.S. at 857 n.20), since the trial judge found as a matter of fact that APRESAZIDE's trade dress was *non*functional. Thus, on this factual record—which is plainly distinguishable from *Ives*—the District Court was perfectly justified in inferring secondary meaning from Bolar's intentional copying, among other things.[17] Indeed, even the district judge in *Ives*, whom Bolar is so fond of quoting, did not rule as a matter of

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17 *Amicus* GPIA is thus wrong in asserting that the courts below held that "the mere act of copying" a product's appearance creates an irrebuttable presumption of secondary meaning that presents "the ultimate Catch-22" to a party who innocently copies a drug's trade dress. (GPIA Br. at 7). On the facts before him, the trial judge here rejected Bolar's claim of innocent motivation and the Third Circuit affirmed that rejection as not being clearly erroneous.

Moreover, the District Court did not infer secondary meaning solely from Bolar's non-innocent copying. For example, as the Court of Appeals pointed out, the District Court also "placed great significance in Bolar's 'consistent use of hydralazine hydrochloride/hydrochlorothiazide as the generic name of the product in suit . . . in finding that patients associate APRESAZIDE with one source." (A. 75).

law that secondary meaning could never be proven in a prescription drug case; he held only that, on the facts before him, the plaintiff there had failed to do so. (488 F. Supp. at 401).

In the final analysis, what Bolar is actually quibbling with is the District Court's assessment of the evidence with respect to secondary meaning, its factual findings with respect to that issue and the Third Circuit's affirmance of those findings as not being clearly erroneous. As we have already demonstrated with respect to nonfunctionality, those are plainly not matters which warrant this Court's review. (*See* pp. 14-18, *supra*). Given the ample evidentiary support for the District Court's finding of secondary meaning (A. 14-18, 24-28, 40-42), Bolar has not made, nor could it make, the "very obvious and exceptional showing of error" which is required before this Court will "undertake to review concurrent findings of fact by two courts below. . . ." *Berenyi* v. *Immigration Director, supra*, 385 U.S. at 635.

* * *

In sum, not only is there no conflict between *Ives* and the lower courts' findings with respect to the tort of "unprivileged imitation," but those findings—which alone are sufficient to support the judgment below—were eminently correct.

B. The Lower Courts' Fact Findings With Respect to the Alternative Tort of "Passing Off" Present No Conflict With This Court's Narrow Disposition in *Ives*.

Like Judge Giles' dissent below, Bolar's Petition devotes considerable attention to an issue which the Third Circuit majority expressly declined to decide—whether *Ives* overruled the "reasonable anticipation" test for the tort of passing off under § 43(a) of the Lanham Act. (Petition at 12-18). As previously noted, the Court of Appeals found it "unnecessary" to reach this "interesting theoretical" issue because the District Court's factual findings with respect to Bolar's intent—which "differ markedly from the findings" in *Ives*—

"implicate Bolar and constitute the prerequisite predicate" for a passing off violation under § 43(a) of the Lanham Act. (A. 80-81, 83 n.10). To grant certiorari to resolve an issue not reached by the Court of Appeals and "unnecessary" to its disposition would clearly violate this Court's venerable rule against rendering advisory opinions.

Bolar's sole response to the Third Circuit's *actual* holding is to argue that the District Court's finding that Bolar intended to induce illegal substitution was unsupported by the evidence and that, therefore, the Court of Appeals erred in not labeling it clearly erroneous. (Petition at 15-18). But, as this Court recently reiterated in *Anderson* v. *City of Bessemer, supra,* 105 S. Ct. at 1512, under Rule 52's "clearly erroneous" test:

> If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Moreover, as Justice White went on to explain in *Anderson,* where a fact finding is "based on determinations regarding the credibility of witnesses"—as it was in this case with respect to Bolar's intent—"Rule 52 demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and the tone of voice that bear so heavily on the listener's understanding of and belief in what is said." (*Id.*)

In light of these guiding principles, there can be no doubt that the Court of Appeals correctly held that the District Court's intent finding was not clearly erroneous.[18] Clearly, that

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18 As this Court has held, the issue of intent "is a pure question of fact, subject to Rule 52's clearly-erroneous standard," *Pullman-Standard* v. *Swint*, 456 U.S. 273, 287-88 (1982), which "depend[s] peculiarly upon the credit given to witnesses by those who see and hear them." United States v. Yellow Cab Co., 338 U.S. 338, 341 (1949).

nding was "plausible in light of the record viewed in its ntirety." In brief, Bolar's president testified that Bolar's sales would be substantially greater if it copied APRESAZIDE's trade dress rather than marketing a non-look-alike generic version, and that Bolar's wholesale customers "prefer[red]" it to duplicate APRESAZIDE's trade dress in order to increase their sales. (R. 206-07, 218-20, 620-23). Given the undisputed testimony of Bolar's medical expert that patients invariably accept different-looking generic substitutes if proper medical and pharmaceutical procedure is followed (A. 22)—that is, if they are told that the generic equivalent is chemically and therapeutically identical—and the undisputed fact that another pharmaceutical manufacturer was "successfully marketing" a non-look-alike generic version of APRESAZIDE (A. 20), it was at least a "permissible view" of the evidence—if not the only plausible one—that Bolar intended that the substantial sales increase it expected from selling its product in a look-alike trade dress would be achieved through *illegal,* not legal, substitution. When coupled with the District Court's unique opportunity to evaluate the credibility of Bolar's president—whose testimony was impeached no fewer than *seven* times by his flatly inconsistent deposition testimony[19]—its finding of an intent to facilitate illegal substitution had more than sufficient evidentiary support to pass muster under Rule 52(a).[20]

Moreover, even if the Third Circuit had affirmed the District Court's § 43(a) "passing off" holding on the basis of the "reasonable anticipation" standard—which it expressly declined to do—there would still be no conflict with *Ives* because that case, unlike this one, did not involve a claim of "passing off" under § 43(a).

As already noted, this Court never reached plaintiff's § 43(a) claim in *Ives.* The reversal of the Second Circuit for failure to

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19 *See* A. 11; R. 188-90, 195-97, 204, 206-18, 221-25, 233-34, 262-66.

20 Bolar is thus wrong in arguing that the trial judge's "finding of intent to induce [was] based on nothing more than copying the appearance of a competitor's product. . . ." (Petition at 18).

comply with Rule 52's clearly erroneous standard was limited to plaintiff's claim of contributory trademark infringement under § 32 of the Lanham Act. Thus, this Court stated that "the judgment of the Court of Appeals that the petitioners violated § 32 of the Lanham Act is reversed." (456 U.S. at 858). In contrast, the case was remanded to the Second Circuit for an "independent review" of plaintiff's § 43(a) claim because—as this Court was at pains to note—that provision "prohibits a broader range of practices than § 32, as may the state unfair competition law. . . ." (*Id.*) Accordingly, *Ives'* purported rejection of the "reasonable anticipation" standard was confined, on its face, to § 32 claims of contributory trademark infringement.

In applying the "reasonable anticipation" standard for the tort of passing off under § 43(a), the District Court followed the lead of *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), where the Third Circuit gave concretion to *Ives'* statement that that provision outlaws a "broader range" of conduct than does § 32. There, citing Judge Hastie's "leading" opinion in *L'Aiglon Apparel, Inc.* v. *Lana Lobell, Inc.*, 214 F.2d 649 (3d Cir. 1954), the Third Circuit explained that "[i]t is well established that Section 43(a) proscribes not only acts that would technically qualify as trademark infringement, but also unfair competitive practices involving actual or potential deception," including the tort of passing off. (625 F.2d at 1065). Because of that "broader" reach, the "reasonable anticipation" standard promotes § 43(a)'s purposes. For, as the District Court reasoned:

> By putting in the hands of pharmacists, through intermediate wholesalers and distributors, a product which admittedly will facilitate illegal passing off, Bolar knowingly creates a real potential for deception, whether or not it is technically guilty of contributory trademark infringement. (A. 46).

What is more, even if *Ives* overruled the "reasonable anticipation" standard for the tort of "passing off" under § 43(a),

and even if the Third Circuit had affirmed the District Court's "passing off" holding under § 43(a) on the basis of that standard, the fact remains that the District Court held *alternatively* that Bolar was guilty of passing off under New Jersey state law, and the Third Circuit affirmed that alternative holding and the full Court denied rehearing *en banc*. (A. 44-47, 76-77, 105). Nor is the Court of Appeals' interpretation of New Jersey law worthy of certiorari review. As this Court declared in *Huddleston* v. *Dwyer,* 322 U.S. 232, 237 (1944), "ordinarily we accept and therefore do not review, save in exceptional cases, the considered determination of questions of state law by the intermediate federal appellate courts." *Accord, Estate of Spiegel* v. *Commissioner,* 335 U.S. 701, 707-08 (1949).[21]

Finally, and apart from all else, it would be improvident for this Court to grant certiorari to review the District Court's "passing off" holdings under federal and state law *unless* it were also prepared to conclude that the District Court's alternative holdings with respect to "unprivileged imitation" under federal and state law merited certiorari review. For otherwise the Court would be violating its long-standing rule against advisory opinions, since those alternative holdings provide an independently sufficient basis to support the judgment below.

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21 Bolar's contention (Petition at 17-18) that the Third Circuit's interpretation of New Jersey law "violate[s]" this Court's holdings in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), is without merit. Indeed, the Second Circuit in *Ives* explicitly rejected the argument that *Sears* and *Compco* preclude trade dress protection under state laws of unfair competition. Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 639-44 (2d Cir. 1979). *Accord,* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1064-65 (3d Cir. 1980); Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203-04 (2d Cir. 1979).

II. Bolar's Purported Public Policy Arguments Are Misplaced and Provide No Basis for the Grant of Certiorari.

Bolar's contention that the judgment below "inhibits the national policy in favor of free competition" and is thus "anti-competitive" (Petition at 30-32) proceeds from the false premise that conduct which constitutes *unfair* competition under federal and state law cannot be proscribed. If that were true, this Court in *Ives* would not have remanded plaintiff's federal and state unfair competition claims for the Second Circuit's "independent[ ] review" (456 U.S. at 858-59); it would simply have held—as the petitioners in that case likewise argued—that "the national policy in favor of free competition" prohibited an injunction against the duplication of a prescription drug's trade dress.

In fact, contrary to Bolar's contention, there is no inconsistency between the interdiction of *unfair* methods of competition and the "national policy in favor of free competition." As the Third Circuit aptly put it in *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, supra,* 625 F.2d at 1067:

> The public policy of both the United States and New Jersey favors free and open competition. But Congress in Section 43(a) of the Lanham Act and New Jersey in its common law of unfair competition have recognized that certain kinds of business activity, while promoting competition in the short run, are in the long run apt to be destructive of competition. The adoption of a distinctive trade dress as a means of identifying a product with its source is a legitimate means for the promotion of the user's business, and permitting piracy of that identifying trade dress can only discourage other manufacturers from making a similar individual promotional effort. Moreover, allowing a manufacturer to be able to acquire and maintain a reputation for consistent good quality is certainly procompetitive. . . . But even if the Lanham Act and the New Jersey law of unfair competition were not in

> the long range interests of competition, preventing deception of the public is itself in the public interest.

Moreover, the injunction granted in this case in no way creates an "artificial barrier" to *legitimate* competition. (Petition at 32). To the contrary, Bolar is entirely free to make and market its generic version of APRESAZIDE in distinctly different-colored capsules and to compete with CIBA's products on the merits—in terms of price, quality and reputation—without appropriating APRESAZIDE's trade dress. As the District Court explicitly found:

> Like Reid-Provident, Bolar could have begun marketing its hydralazine hydrochloride/hydrochlorothiazide combinations in March 1982 in differently colored capsules than APRESAZIDE, if not tablet form, and achieved the same strong market position which it admits Reid-Provident has achieved. (A. 48).

Nor, contrary to Bolar's contention, is the public policy underlying generic drug substitution laws in any way offended by the enforcement of CIBA's federal and state rights against Bolar's unfair competition. For as one court has perceptively explained:

> [T]he raison d'etre of generic substitution laws is to give consumers equivalent pharmaceutical products at lower prices. Consumers who unknowingly receive a generic but pay brand name prices do not derive any of the benefits of the generic substitution laws. Simulation of Persantine's trade dress renders this deprivation of intended benefits possible.

Boehringer Ingelheim G.m.b.H. v. *Pharmadyne Laboratories*, 532 F. Supp. 1040, 1067 (D.N.J. 1980) (Lacey, J.).[22]

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22 Similarly, in construing New York's generic substitution law, that state's highest court unanimously stated:

> The "Generic Drug Substitution Law" does not promote unfair competition or the infringement of drug patents or trade-marks;

Finally, *amicus* GPIA incorrectly asserts that a patient's right to "informed consent"—which the District Court invoked in support of its injunction—"has no identifiable counterpart in the state or federal laws of unfair competition. . . ." (GPIA Br. at 4). In fact, in enacting the Lanham Act, Congress made it clear that protection of a consumer's informed "choice between competing articles" was at the heart of the statute, and that trademarks promote that objective by "enabling the buyer to distinguish one [competing article] from the other."[23] Indeed, this Court has explicitly recognized the right of "informed consent" which GPIA contends does not exist:

> If consumers or dealers prefer to purchase a given article because it was made by a particular manufacturer or class of manufacturers, they have a right to do so, and this right cannot be satisfied by imposing upon them an exactly similar article, or one equally as good, but having a different origin.

F.T.C. v. *Colgate-Palmolive Co.*, 380 U.S. 374, 388 (1965), *quoting F.T.C.* v. *Royal Milling Co.*, 288 U.S. 212, 216 (1933).[24]

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nor does the Law create any defenses to such claims. . . . [P]laintiff's rights and remedies under the patent and trade-mark laws are the same now as they were prior to the passage of the law.

Pharmaceutical Manufacturers Association v. Whalen, 54 N.Y.2d 486, 495, 446 N.Y.S.2d 217, 220-21, 430 N.E.2d 1270, 1273-74 (1981).

Justice White's reliance on state generic substitution laws in his concurrence in *Ives* was predicated on a district court fact finding that CYCLOSPASMOL's trade dress was functional. (456 U.S. at 861-62). Here, in contrast, the trial judge found as a matter of fact that APRESAZIDE's trade dress was nonfunctional—a fact finding which the Third Circuit held was not clearly erroneous.

23 S. Rep. No. 1333, 79th Cong., 2d Sess., *reprinted in* U.S. Code Cong. Serv. at p. 1275 (1946).

24 GPIA's absurd contention that patients do not care about the source of their medication (GPIA Br. at 12) is contradicted by the District Court's finding below that when patients are given a choice between a brand name drug and a generic equivalent they often choose to remain with the brand name medication (A. 21-22)—a finding supported by the testimony of Bolar's own medical and pharmacy experts. (R. 509,

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Petition should be denied.

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Respectfully submitted,

RANDOLPH S. SHERMAN
425 Park Avenue
New York, New York 10022
(212) 407-8000

Attorney for Respondent

Of Counsel:

MILTON HANDLER
RICHARD A. DE SEVO
Kaye, Scholer, Fierman, Hays & Handler
425 Park Avenue
New York, New York 10022

FREDERICK L. WHITMER
Pitney, Hardin, Kipp & Szuch
163 Madison Avenue, CN 1945
Morristown, New Jersey 07960

GARY S. FREEDMAN
MIRIAM LANE SPARROW
CIBA-GEIGY Corporation
556 Morris Avenue
Summit, New Jersey 07901

583, 586, 588). Equally absurd is GPIA's claim that the District Court's reliance on informed consent "is an unwarranted attempt at judicial legislation to supplement the State substitution laws." (GPIA Br. at 4). In fact, state substitution laws like Illinois' *require* informed consent before permitting generic substitution. (A. 23 n.7).

PROOF OF SERVICE

I, Randolph S. Sherman, attorney for Respondent herein, and a member of the Bar of the Supreme Court of the United States, do hereby certify that on the 8th day of May 1985, I caused to be served by hand three copies of the foregoing Brief for Respondent CIBA-GEIGY Corporation in Opposition to Petition for Writ of Certiorari on Robert V. Marrow, Salon, Marrow, Dyckman & Trager, 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

Dated: May 8, 1985

RANDOLPH S. SHERMAN
425 Park Avenue
New York, New York 10022
(212) 407-8000

Attorney for Respondent